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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,668	02/21/2007	Thomas Niklaus Hangartner	WRU 0239 PA	8346
23368 7590 02/08/2008 DINSMORE & SHOHL LLP ONE DAYTON CENTRE, ONE SOUTH MAIN STREET SUITE 1300 DAYTON, OH 45402-2023			EXAMINER SONG, HOON K	
			ART UNIT 2882	PAPER NUMBER
			MAIL DATE 02/08/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/550,668

Applicant(s)

HANGARTNER ET AL.

Examiner

Hoon Song

Art Unit

2882

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-35 is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/06, 1/27/06</u>   | 6) <input type="checkbox"/> Other: ____                           |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 1/9/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Some of the document is not present (see attached copy of IDS).

### ***Claim Objections***

Claim 28 is objected to because of the following informalities:

In claim 28 line 4, "image portion" should read --imaging portion--.

Similar informality exist. Appropriate correction for all claims is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-15, 18-23 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang (US 2003/0063704A1).

Regarding claim 1, Lang teaches a method to screen for osteoporosis damage to a patient's bones comprising:

placing in the mouth of the patient adjacent to a mandibular bone being tested, a dental radiographic absorptiometric device comprising at least one calibration element (paragraph 127);

applying X-ray energy to said dental radiographic absorptiometric device simultaneously through said mandibular bone and said at least one calibration element to generate both a bone absorptive record from said mandibular bone and a calibration element absorptive record from said at least one calibration element (paragraph 127); and

analyzing said bone absorptive record against said calibration element absorptive record to determine the extent, if any, of the osteoporosis damage to said mandibular bone (paragraph 24 and 104).

Regarding claim 2, Lang teaches said X-ray energy is provided by a device selected from the group consisting of single-energy and dual-energy devices (paragraph 8).

Regarding claim 3, Lang teaches said at least one calibration element is at least one calibration wedge and at least one beam filter (figure 10).

Regarding claim 4, Lang teaches said dental radiographic absorptiometric device is selected from the group consisting of digital and non-digital radiographic absorptiometric devices (paragraph 115).

Regarding claim 5, Lang teaches said dental radiographic absorptiometric device is selected from the group consisting of a charge coupled device camera, CMOS wafers, electronic image sensors, and X-ray film (paragraph 115).

Regarding claim 6, Lang teaches said dental radiographic absorptiometric device comprises an image sensor with a fluorescent layer (paragraph 115).

Regarding claim 7, Lang teaches a region of interest in the mandible of the patient (figure 9).

Regarding claim 8, Lang teaches digitizing said bone absorptive record and said calibration element absorptive record (paragraph 115).

Regarding claim 9, Lang teaches said region of interest is trabecular bone in the mandible (figure 9).

Regarding claim 10, Lang teaches said region of interest is trabecula in the area between roots of the second bicuspid and the first molar and from the superior border of the mandibular to approximately one-half of the molar root length (figure 9).

Regarding claim 13, Lang teaches a dental radiographic absorptiometric device adapted for osteoporosis screening using a standard dental X-ray machine and being locatable in a patient's mouth, said device comprising:

- an image portion having a first surface (figures 2-3);

- a biting block portion 100 attached to the first surface of said image portion, said biting block portion defining a cavity (figures 2-3); and

- at least one calibration element 120 accommodated in said cavity of said biting block portion.

Regarding claim 14, Lang teaches said imaging portion is an enclosure sized to accommodate standard dental X-ray film (figures 2-3).

Regarding claim 15, Lang teaches said imaging portion is an electronic sensor (paragraph 115).

Regarding claim 18, Lang teaches said cavity of said biting block portion extends from said first surface of said imaging portion completely through said biting block portion (figures 2-3).

Regarding claim 19, Lang teaches said biting block portion extends a distance from said imaging portion such that the device may be fully enclosed in the patient's mouth (figures 2-3).

Regarding claim 20, Lang teaches said biting block portion extends a distance from said imaging portion such that the device protrudes partially from the patient's mouth (figures 2-3).

Regarding claim 21, Lang teaches said biting block portion and said imaging portion is any other suitable low attenuating materials (figures 2-3).

Regarding claim 22, Lang teaches said at least one calibration element is any other suitable calibration material (paragraph 4).

Regarding claim 23, Lang teaches said at least one calibration element is selected from the group consisting of step wedges, tapered wedges, and combinations thereof (figure 10).

Regarding claim 25, Lang teaches said at least one calibration element is two calibration wedges (left and right calibration wedges, figure 10).

Regarding claim 26, Lang teaches said calibration wedges are provided in a counter side-by-side orientation (figure 10).

Regarding claim 27, Lang teaches said calibration wedges are provided in a side-by-side orientation (figure 10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12, 16-17, 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang.

Regarding claims 11-12, Lang fails to teach the method of subtracting soft tissue effects from digital images of said bone absorptive record and said calibration element absorptive record and comparing intensities of said digital images at specific locations to determine bone density and bone mineral content.

Soft tissue subtracting method is known in the art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the method of Lang with the known soft tissue subtracting method, since the method would provide better S/N ratio for the calibration.

Regarding claims 16-17, Lang teach fails to teach said electronic sensor is a CCD camera provided with a fluorescent screen.

CCD based x-ray detector is known in the art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the detector of Lang with the known CCD based detector, since it would provide benefit of availability for manufacturing while providing proper detecting results.

Regarding claim 24, Lang teaches said at least one calibration element is a step wedge having dimensions of about 3 mm by about 25 mm (paragraph 118).

However fails to teach steps of thicknesses ranging from about 0.05 mm to about 0.33 mm.

It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the calibration element of Lang with certain thickness since it would provide better diagnostic data.

Regarding claim 28, Lang fails to teach said calibration wedges are provided in crisscross arrangement.

It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the calibration element of Lang in crisscross arrangement since it would provide better diagnostic data.

#### ***Allowable Subject Matter***

Claims 29-35 are allowed over prior art.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 29-35, the prior art fails to teach a dental radiographic absorptiometric device adapted for osteoporosis screening using a standard dental X-ray machine and being locatable in a patient's mouth, the device having at least one calibration element and at least one of an upper beam filter accommodated in the cavity of the biting block portion and at least one of a lower beam filter provided to the imaging portion below the biting block portion as claimed in independent claim 29.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hoon Song whose telephone number is (571) 272-2494. The examiner can normally be reached on 9:30 AM - 7 PM, Monday - Friday.

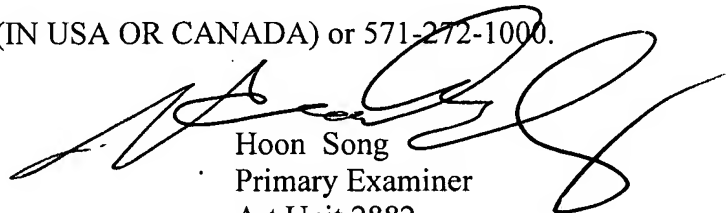


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272 - 2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Hoon Song  
Primary Examiner  
Art Unit 2882